

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA  
CLARKSBURG DIVISION**

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Case No. 1:22-cv-00061-TSK

**Claim Construction Hearing:  
January 6, 2023, 10:00 am**

**JOINT CLAIM CONSTRUCTION CHART**

Pursuant to the Court’s Scheduling Order (ECF No. 87), Plaintiff Regeneron Pharmaceuticals, Inc. (“Regeneron”) and Defendant Mylan Pharmaceuticals Inc. (“Mylan”) submit the following Joint Claim Construction Chart to assist with the Court’s preparation for the hearing scheduled for January 6, 2023.

**I. JOINT POSITION ON CLAIM CONSTRUCTION BRIEFING**

The Court’s Scheduling Order directs the parties to submit their positions concerning the length of any claim construction briefing. The parties have conferred and respectfully submit that their respective opening and responsive claim construction briefs be limited to 30 pages.

**II. CLAIM CONSTRUCTION DISPUTES & SUPPORTING INTRINSIC EVIDENCE**

The parties request that the Court resolve the following claim construction disputes.

Claim Term [Requesting Party]	Regeneron's Proposed Construction and Intrinsic Evidence <sup>1</sup>	Mylan's Proposed Construction and Intrinsic Evidence <sup>2, 3</sup>
<p>Best Corrected Visual Acuity ('601 patent, claims 5-6, 15-16, 23-24, and 31-32; '572 patent, claims 2, 3, 8, 10, 17, 21, and 30)</p> <p>[Regeneron]</p>	<p>the best visual acuity that can be achieved with the use of a corrective lens</p> <p>'572 patent, 8:32-36, 9:26-27, 9:50-53, 10:28-30, 10:50-57, 12:23-27, Table 1.2<sup>4</sup></p>	<p>Plain and ordinary meaning:</p> <p><i>Best Corrected Visual Acuity (BCVA), measured in letters, a clinical trial endpoint / measurement</i></p> <p>The entire specification for the 601 patent, including but not limited to: References Cited; Related Applications; Examples (in particular, Examples 1, 3-4); Claims; and, in particular: 7:26-45; 8:23-27; 9:18-19; 9:49-51; 10:26-28; 12:33-40.</p> <p>The entire prosecution file history for the 601 patent, including but not limited to: RGN-EYLEA-MYLAN-00001666-1667; RGN-EYLEA-MYLAN-00002482-2483; RGN-EYLEA-MYLAN-00002484-2493; RGN-EYLEA-MYLAN-</p>

<sup>1</sup> Regeneron disagrees with Mylan's characterizations in footnotes 3 and 7 of the parties' process for identifying terms, exchanging preliminary constructions, and preparing this submission and its allegations of waiver.

<sup>2</sup> Mylan reserves all rights to assert that the claims of the Asserted Patents are invalid under 35 U.S.C. § 112 as indefinite and/or lacking enablement and/or lacking written description. Nothing in this Joint Claim Construction Chart shall be interpreted as a concession by Mylan that the claim terms identified herein satisfy the 35 U.S.C. § 112 requirements.

<sup>3</sup> Mylan reserves all rights to argue that Regeneron waived the opportunity to have the Mylan Proposed Terms construed for failure to present an actual construction of each term beyond their statement that each be afforded its "Plain and ordinary meaning in view of the claims and specification." Mylan requested, but Regeneron refused to provide, explanations of what Regeneron considers to be the "plain and ordinary meaning" of each disputed claim term.

<sup>4</sup> Throughout this document, to the extent a disclosure is cited in the '572 or '601 patents, the equivalent disclosure in the other patent is also incorporated herein.

Claim Term [Requesting Party]	Regeneron's Proposed Construction and Intrinsic Evidence <sup>1</sup>	Mylan's Proposed Construction and Intrinsic Evidence <sup>2, 3</sup>
		<p>00004636; RGN-EYLEA-MYLAN-00005312-5313; RGN-EYLEA-MYLAN-00005370; RGN-EYLEA-MYLAN-00005433-5434; RGN-EYLEA-MYLAN-00005754-5755; RGN-EYLEA-MYLAN-00002494-4635; RGN-EYLEA-MYLAN-00006349; RGN-EYLEA-MYLAN-00006811-6812.</p> <p>The entire specification for the 572 patent, including but not limited to: References Cited; Related Applications; Examples (in particular, Examples 1, 3-4); Claims; and, in particular: 8:32-36; 9:26-27; 10:28-30.</p> <p>The entire prosecution file history for the 601 and 572 patent, including but not limited to: RGN-EYLEA-MYLAN-00016655-17043.</p> <p>The entire record for <i>Inter Partes</i> Review Nos. IPR2021-00880 (U.S. Patent No. 9,669,069), IPR2021-00881 (U.S. Patent No. 9,254,338), IPR2022-01225 (U.S. Patent No. 10,130,681), IPR2022-01226 (U.S. Patent No. 10,888,601), IPR2022-01524 (U.S. Patent No. 11,253,572).</p>
chemically defined medium (CDM) ('715 patent, claims 1, 15, and 16; '280 patent, claims 1 and 5; '532 patent, claims 1 and 19)	a synthetic growth medium in which the identity and concentration of all the ingredients are defined	<i>a synthetic growth medium in which the identity and concentration of all the ingredients are defined and does not contain bacterial, yeast, animal, or plant extracts or</i>

Claim Term [Requesting Party]	Regeneron's Proposed Construction and Intrinsic Evidence <sup>1</sup>	Mylan's Proposed Construction and Intrinsic Evidence <sup>2, 3</sup>
[Regeneron]	'715 patent, 30:44-31:5. <sup>5</sup>	<p><i>hydrolysates, animal serum, or plasma</i></p> <p>The entire specification for the '715 patent,<sup>6</sup> including but not limited to: References Cited, Related Applications, Title, Abstract, Figures, Examples (cols. 98-146), Asserted Claims, and, in particular, the following: Figs. 5-8, 12A-12C, 26-31; 2:3-3:32; 5:51-6:28; 7:9-20; 17:58-64; 21:41-24:21; 24:49-29:3; 29:38-30:24; 30:44-31:48; 55:24-37; 58:63-60:57; 62:43-64:27; 69:26-76:63; 93:41-94:53.</p> <p>The entire specification for the '280 patent, including but not limited to: Related Applications, Title, Abstract, Figures, Examples (cols. 97-142), Asserted Claims, and, in particular, the following: Figs. 5-8, 12A-12C, 26-31; 1:65-3:28; 5:47-6:24; 7:5-16; 15:26-33; 19:9-21:55; 22:15-26:40; 27:6-58; 28:10-29:14; 53:61-54:7; 57:41-59:33; 60:50-63:4; 68:4-75:40; 92:19-93:30.</p> <p>The entire specification for the '532 patent, including but not limited to: Related Applications, Title, Abstract, Figures,</p>

<sup>5</sup> Throughout this document, to the extent a disclosure is cited in the '715, '280, or '532 patents, the equivalent disclosures in the other patents are also incorporated herein.

<sup>6</sup> Throughout this document, to the extent a disclosure is cited in the '715, '280, or '532 patents, the equivalent disclosures in the other patents are also incorporated herein.

Claim Term [Requesting Party]	Regeneron's Proposed Construction and Intrinsic Evidence <sup>1</sup>	Mylan's Proposed Construction and Intrinsic Evidence <sup>2, 3</sup>
		<p>Examples (cols. 98-146), Asserted Claims, and, in particular, the following: Figs. 5-8, 12A-12C, 26-31; 2:5-3:36; 5:55-6:32; 7:13-23; 17:42-48; 21:25-24:4; 24:32-28:57; 29:24-30:9; 30:28-31:33; 55:6-19; 58:44-60:36; 62:22-64:6; 69:6-76:40; 93:19-94:30.</p> <p>The entire prosecution file history for the 715, 280 and 532 patents, including but not limited to RGN-EYLEA-MYLAN-00024664-693; RGN-EYLEA-MYLAN-00024866-896; RGN-EYLEA-MYLAN-00025995-6097; RGN-EYLEA-MYLAN-00026848-912; RGN-EYLEA-MYLAN-00026920-7029; RGN-EYLEA-MYLAN-00027425-634; RGN-EYLEA-MYLAN-00027635-671; RGN-EYLEA-MYLAN-00027672-691; RGN-EYLEA-MYLAN-00029579-607; RGN-EYLEA-MYLAN-00029780-810; RGN-EYLEA-MYLAN-00030829-931; RGN-EYLEA-MYLAN-00031197-306; RGN-EYLEA-MYLAN-00031310-374; RGN-EYLEA-MYLAN-00031691-900; RGN-EYLEA-MYLAN-00031984-020; RGN-EYLEA-MYLAN-00032021-040; RGN-EYLEA-MYLAN-00032839-861; RGN-EYLEA-MYLAN-00033395-417; RGN-EYLEA-MYLAN-00033583-609; RGN-EYLEA-MYLAN-00033643-646</p> <p>U.S. Patent No. 11,312,936</p>

Claim Term [Requesting Party]	Regeneron's Proposed Construction and Intrinsic Evidence <sup>1</sup>	Mylan's Proposed Construction and Intrinsic Evidence <sup>2, 3</sup>
		<p>U.S. Provisional Patent Application No. 62/944,635, including but not limited to [0046] ("CDM offers greater reproducibility / consistency over hydrolysate-based media.) and [00166] ("A CDM does not include hydrolysate such as, for example, soy hydrolysate."); <i>id.</i> at [00165], [00368]</p> <p>U.S. Provisional Patent Application No. 63/065,012, including but not limited to [0009], [0027], [0182], [0315]-[0318], [0466], [0494], [0544], [0545]</p> <p>European Patent Application No. 20764873.4, including, but not limited to 10/4/2022 Reply; 4/8/2022 Reply; PCT/US2020/046809, including but not limited to [0010], [0028], [0184], [0317]-[0320], [0496], [0546]-[0547]</p> <p>European Patent Application No. 20765400.5, including, but not limited to 4/8/2022 Reply; 10/4/2022 Reply; PCT/US2020/046831, including but not limited to [0010], [0028], [0184], [0317]-[0320], [0496], [0546]-[0547]</p> <p>European Patent Application No. 20765397.3, including, but not limited to 4/8/2022 Reply; 10/4/2022 Reply; PCT/US2020/046823, including but not limited to [0010], [0028],</p>

Claim Term [Requesting Party]	Regeneron's Proposed Construction and Intrinsic Evidence <sup>1</sup>	Mylan's Proposed Construction and Intrinsic Evidence <sup>2, 3</sup>
		<p>[0184], [0317]-[0320], [0496], [0546]-[0547]</p> <p>European Patent Application No. 20775971.3, including, but not limited to 4/8/2022 Reply; 10/4/2022 Reply; PCT/US2020/046842, including but not limited to [0010], [0028], [0184], [0317]-[0320], [0496], [0546]-[0547]</p> <p>European Patent Application No. 20765403.9, including, but not limited to 10/4/2022 Reply; PCT/US2020/046846, including but not limited to [0010], [0028], [0184], [0317]-[0320], [0496], [0546]-[0547]</p>
<p>anti-oxidants ('715 patent, claims 1, 3, 4, 16)</p> <p>[Regeneron]</p>	<p>Plain and ordinary meaning in view of the claims and specification, which is not limited to “taurine, hypotaurine, glycine, thioctic acid, glutathione, choline chloride, hydrocortisone, Vitamin C, Vitamin E and combinations thereof”</p> <p>'715 patent, 21:61-66, 23:52-63, 23:64-24:1, 24:17-21, 72:9-13, 75:4-9, 75:10-54, 120:46-123:18, 140:30-145, 261:20-22, 261:27-30, 261:31-35, 261:62-64, 262:35-37, 263:1-3, Fig. 25, Fig. 28</p> <p>U.S. Patent Application No. 16/996,030, August 18, 2020</p>	<p>No construction needed.</p> <p>The entire specification for the 715 patent, including but not limited to: References Cited, Related Applications (including 62/944,635 at [00219]; Example 16), Title, Abstract, Figures, 75:4-9; Examples (including Examples 5 and 9, and associated Figures), and Asserted Claims.</p> <p>The entire prosecution file history for the 715 patent.</p>

Claim Term [Requesting Party]	Regeneron's Proposed Construction and Intrinsic Evidence <sup>1</sup>	Mylan's Proposed Construction and Intrinsic Evidence <sup>2, 3</sup>
	<p>Claims for Consideration at 216-220.</p> <p>U.S. Patent Application No. 16/996,030, December 2, 2020 Non-Final Office Action at 9.</p> <p>U.S. Patent Application No. 16/996,030, December 2, 2020 Non-Final Office Action at 12, 17.</p> <p>U.S. Patent Application No. 16/996,030, Dec. 4, 2020 Preliminary Amendment at 213-17.</p> <p>U.S. Patent Application No. 16/996,030, March 2, 2021 Amendment to Claims at 3-8.</p> <p>U.S. Patent Application No. 16/996,030, March 2, 2021 Response to Non-Final Office Action at 16-17, 22.</p> <p>U.S. Patent Application No. 16/996,030, March 24, 2021 Final Office Action at 12-23.</p> <p>U.S. Patent Application No. 16/996,030, May 6, 2021 Draft Amendments to Claims at 2-7.</p> <p>U.S. Patent Application No. 16/996,030, June 11, 2021 Response After Final Rejection at 2-6.</p> <p>U.S. Patent Application No. 16/996,030, June 14, 2021</p>	

Claim Term [Requesting Party]	Regeneron's Proposed Construction and Intrinsic Evidence <sup>1</sup>	Mylan's Proposed Construction and Intrinsic Evidence <sup>2, 3</sup>
	<p>Examiner Interview Summary Record.</p> <p>U.S. Patent Application No. 16/996,030, June 28, 2021 Examiner Interview Summary Record.</p> <p>U.S. Patent Application No. 16/996,030, June 28, 2021 Notice of Allowability at 3-5.</p>	
<p>formulated as an isotonic solution ('572 patent, claims 6, 12, 18, 22)</p> <p>[Regeneron]</p>	<p>Plain and ordinary meaning in view of the claims and specification, which does not require the presence of glucose.</p> <p>'572 patent, 6:11-12, 6:22-30, 6:39-41, 15:64-17:37.</p> <p>'572 patent, claim 1; claim 15.</p>	<p>No construction needed.</p> <p>The entire specification for the 572 patent, including but not limited to: References Cited, Related Applications, Title, Abstract, Figures, Examples, Asserted Claims, and, in particular, 6:18-34.</p> <p>The entire prosecution file history for the 572 patent.</p>
<p>"[present in] native conformation"</p> <p>('865 patent, claims 1, 16, 17)</p> <p>[Mylan]</p>	<p>This term does not need to be construed outside of the context of the limitations in which it appears (e.g., "wherein at least 98% of the VEGF antagonist is present in native conformation following storage at 5° C. for two months as measured by size exclusion chromatography."). Within that context, it should be given its plain and ordinary meaning in view of the claims and the specification</p>	<p>Plain and ordinary meaning:</p> <p><i>[present in] a form that does not exhibit chemical or physical instability</i></p> <p>The entire specification for the 865 patent, including but not limited to: References Cited, Related Applications, Title, Abstract, Figures, Examples 1-7, Asserted Claims, and, in particular, the following: 1:40-2:10; 2:14-65; 3:1-57; 3:58-4:6; 4:7-5:3; 5:4-27; 5:51-60; 5:61-</p>

Claim Term [Requesting Party]	Regeneron's Proposed Construction and Intrinsic Evidence <sup>1</sup>	Mylan's Proposed Construction and Intrinsic Evidence <sup>2, 3</sup>
	<p>'865 patent, 5:51-6:2, 6:27-58, 6:60-7:25, 7:42-51, 8:40-44, 9:1-3, 9:28-30, 9:55-57, 10:24-22, 10:50-52, 11:11-15, 12:11-13, Tables 1-8.</p> <p>U.S. Patent Application No. 11/818,463, Jan. 14, 2007 Specification.</p> <p>U.S. Patent Application No. 16/159,269, July 22, 2019 Applicant Remarks at 5-6.</p> <p>U.S. Patent Application No. 16/582,486, Mar. 2, 2021 Applicant Remarks at 15-16.</p> <p>U.S. Patent Application No. 16/739,559, Jan. 10, 2020 Applicant Remarks at 4, Amendments to the Claims at 2.</p> <p>U.S. Patent Application No. 16/739,559, May 5, 2021 Applicant Remarks at 11-12.</p>	<p>6:2; 6:6-23; 6:27-58; 6:60-7:25; 7:26-8:3.</p> <p>The entire prosecution file history for the 865 patent, including but not limited to: RGN-EYLEA-MYLAN-00015146-48; RGN-EYLEA-MYLAN-00015158-64.</p>
<p>"organic co-solvent"</p> <p>('865 patent)</p> <p>[Mylan]</p>	<p>Plain and ordinary meaning in view of the claims and specification; to the extent there is a dispute as to claim scope, "organic co-solvent" includes polysorbate 20, polysorbate 80, polyethylene glycol, or propylene glycol, or a combination thereof</p> <p>'865 patent, 2:39-43, 2:33-38, 2:49-52, 3:11-16, 3:28-31, 4:11-17, 7:2-7.</p>	<p>Plain and ordinary meaning:</p> <p><i>an organic substance added to a primary solvent to increase the solubility of said VEGF antagonist</i></p> <p>The entire specification for the 865 patent, including but not limited to: References Cited, Related Applications, Title, Abstract, Figures, Examples 1-5, Asserted Claims, and, in particular, the following: 2:39-</p>

Claim Term [Requesting Party]	Regeneron's Proposed Construction and Intrinsic Evidence <sup>1</sup>	Mylan's Proposed Construction and Intrinsic Evidence <sup>2, 3</sup>
	<p>'865 patent, claims 1-5, 26-30.</p> <p>U.S. Patent Application No. 11/818,463, Jan. 30, 2009 Non-Final Rejection, at 5.</p> <p>U.S. Patent Application No. 13,914,996, Oct. 8, 2013 Non-Final Rejection, at 4-5.</p> <p>U.S. Patent Application No. 14/330,096, Apr. 2, 2015 Non-Final Rejection, at 7.</p>	<p>42; 2:49-50; 3:28-31; 4:15-16; 7:2-7.</p> <p>The entire prosecution file history for the 865 patent.</p>
<p>"a clarified harvest of cells cultured in a chemically defined medium (CDM)";</p> <p>"a clarified harvest of a cell cultured in a chemically defined medium (CDM)"</p> <p>"harvested from a host cell cultured in a chemically defined medium (CDM)";</p> <p>"aflibercept from a clarified harvest...wherein said aflibercept is expressed by cells cultured in a chemically defined medium (CDM)"</p> <p>"aflibercept from a clarified harvest cultured (CDM)"</p> <p>('280 patent, claims 1, 5; '532 patent, claims 1,</p>	<p>Plain and ordinary meaning in view of the claims and specification; to the extent there is a dispute as to claim scope, this limitation does not exclude methods where the cell is subsequently cultured in a non-chemically defined medium</p> <p>'715 patent, 2:21-54, 5:53-57, 17:41-64, 21:41-22:59, 29:38-30:13, 30:44-31:48, 32:59-34:17, 54:43-54, 55:24-52, 58:63-59:20, 71:33-76:51, 81:53-94:53, 93:42-94:53, 99:35-60, 99:61-104:57, 120:45-123:18, 123:20-126:28, 140:25-145:30, Fig. 59.</p> <p>U.S. Application No. 17/489,495, Nov. 3, 2021 Non-Final Rejection at 3-4.</p> <p>U.S. Application No. 17/489,495, December 16, 2021</p>	<p>Plain and ordinary meaning:</p> <p><i>harvested from / a clarified harvest made using CDM (i.e., a synthetic growth medium in which the identity and concentration of all the ingredients are defined and does not contain bacterial, yeast, animal, or plant extracts or hydrolysates, animal serum, or plasma).</i></p> <p>The entire specification for the 715 patent, including but not limited to: References Cited, Related Applications, Title, Abstract, Figures, Examples (cols. 98-146), Asserted Claims, and, in particular, the following: Figs. 5-8, 12A-12C, 26-31; 2:3-3:32; 5:51-6:28; 7:9-20; 17:58-64; 21:41-24:21; 24:49-29:3; 29:38-30:24; 30:44-31:48; 55:24-37; 58:63-60:57; 62:43-64:27; 69:26-76:63; 93:41-94:53.</p>

Claim Term [Requesting Party]	Regeneron's Proposed Construction and Intrinsic Evidence <sup>1</sup>	Mylan's Proposed Construction and Intrinsic Evidence <sup>2, 3</sup>
<p>19; '715 patent, claims 1, 15, 16)</p> <p>[Mylan]</p>	<p>Response to Non-Final Office Action at 3, 5, 7.</p>	<p>The entire specification for the 280 patent, including but not limited to: Related Applications, Title, Abstract, Figures, Examples (cols. 97-142), Asserted Claims, and, in particular, the following: Figs. 5-8, 12A-12C, 26-31; 1:65-3:28; 5:47-6:24; 7:5-16; 15:26-33; 19:9-21:55; 22:15-26:40; 27:6-58; 28:10-29:14; 53:61-54:7; 57:41-59:33; 60:50-63:4; 68:4-75:40; 92:19-93:30.</p> <p>The entire specification for the 532 patent, including but not limited to: Related Applications, Title, Abstract, Figures, Examples (cols. 98-146), Asserted Claims, and, in particular, the following: Figs. 5-8, 12A-12C, 26-31; 2:5-3:36; 5:55-6:32; 7:13-23; 17:42-48; 21:25-24:4; 24:32-28:57; 29:24-30:9; 30:28-31:33; 55:6-19; 58:44-60:36; 62:22-64:6; 69:6-76:40; 93:19-94:30.</p> <p>The entire prosecution file history for the 280, 532 and 715 patents, including but not limited to RGN-EYLEA-MYLAN-00030241-260; EYLEA-MYLAN-000325-331; RGN-EYLEA-MYLAN-00032370-392; RGN-EYLEA-MYLAN-00033583-609; RGN-EYLEA-MYLAN-00033683-692; RGN-EYLEA-MYLAN-00043826-833; RGN-EYLEA-MYLAN-00043900-4138</p>

Claim Term [Requesting Party]	Regeneron's Proposed Construction and Intrinsic Evidence <sup>1</sup>	Mylan's Proposed Construction and Intrinsic Evidence <sup>2, 3</sup>
		<p>U.S. Provisional Patent Application No. 62/944,635, including but not limited to [0046] and [00166]</p> <p>U.S. Provisional Patent Application No. 63/065,012</p> <p>European Patent Application No. 20764873.4, including, but not limited to 10/4/2022 Reply; 4/8/2022 Reply; 6/28/2021 Priority Document PCT /US2020/046809</p> <p>European Patent Application No. 20765400.5, including, but not limited to 4/8/2022 Reply; 10/4/2022 Reply</p> <p>European Patent Application No. 20765397.3, including, but not limited to 4/8/2022 Reply; 10/4/2022 Reply</p> <p>European Patent Application No. 20775971.3, including, but not limited to 4/8/2022 Reply; 10/4/2022 Reply</p> <p>European Patent Application No. 20765403.9, including, but not limited to 10/4/2022 Reply</p>
<p>“wherein exclusion criteria for the patient include”</p> <p>(’601 patent, claims 9, 17, 25, 33; ’572 patent, claim 14)</p> <p>[Mylan]</p>	<p>The claim limitations are appropriately construed as: “assessing the patient for (1) active ocular inflammation; and (2) active ocular or periocular infection, and administering aflibercept to the patient on the</p>	<p>The “exclusion criteria” represent informational content regarding the patient that is not functionally related to other claim elements, and therefore, should be considered “printed matter” that are accorded “no patentable weight.”</p>

Claim Term [Requesting Party]	Regeneron's Proposed Construction and Intrinsic Evidence <sup>1</sup>	Mylan's Proposed Construction and Intrinsic Evidence <sup>2, 3</sup>
	<p>basis of the foregoing assessment.”</p> <p>The “patient” is not limited to a clinical trial subject.</p> <p>These limitations are not “printed matter” and the limitations are entitled to patentable weight.</p> <p>’601 patent, 2:4-11, 4:1-12, 4:13-22, 4:23-46, 8:9-15, 8:39-44, 8:66-9:7, 9:58-10:4, 10:5-11, 10:24-40, 17:9-15.</p> <p><i>See also</i> U.S. Patent Application No. 16/159,282, August 14, 2019 Applicant Remarks at 6-9.</p>	<p>To the extent the Court determines that this term should be accorded patentable weight, it should be construed as follows<sup>7</sup>:</p> <p><i>“wherein exclusion criteria for the patient to be eligible in the clinical study of the said method for treating include”</i></p> <p>The entire specification for the 601 patent, including but not limited to: References Cited, Related Applications, Title, Abstract, Figures, Examples (in particular, Example 4), and Asserted Claims.</p> <p>The entire prosecution file history for the 601 patent, including but not limited to: RGN-EYLEA-MYLAN-00001666; RGN-EYLEA-MYLAN-00002269; RGN-EYLEA-MYLAN-00002486; RGN-EYLEA-MYLAN-00002501-2502; RGN-EYLEA-MYLAN-00001688-1689; RGN-EYLEA-MYLAN-00001721-00004635 (list of over 100 clinicaltrials.org publications, setting forth “Exclusion Criteria”).</p> <p>The entire specification for the 572 patent, including but not limited to: References Cited,</p>

<sup>7</sup> Mylan objects to the inclusion of Regeneron’s argument that “[t]he ‘patient’ is not limited to a clinical trial subject.” The claim term “patient” was not proposed for construction by either party. Mylan reserves all rights to argue that Regeneron waived the opportunity to have the claim term “patient” construed.

<b>Claim Term [Requesting Party]</b>	<b>Regeneron's Proposed Construction and Intrinsic Evidence<sup>1</sup></b>	<b>Mylan's Proposed Construction and Intrinsic Evidence<sup>2, 3</sup></b>
		<p>Related Applications, Title, Abstract, Figures, Examples (in particular, Example 4), and Asserted Claims.</p> <p>The entire prosecution file history for the 572 patent.</p>

### III. STIPULATED CONSTRUCTIONS

The parties exchanged proposed terms for construction and met and conferred regarding various claim construction disputes. In view of the case schedule and issues raised, the parties have stipulated to the following claim constructions for purposes of this case:

<b>Claim Term</b>	<b>Agreed-Upon Construction</b>
glycosylated ('865 patent, claim 1)	containing at least one amino acid residue with an attached carbohydrate
cumulative concentration ('715 patent, claims 1, 15, and 16)	the cumulative amount of a component divided by the volume of liquid in the bioreactor at the beginning of the production batch, including the contribution to the starting volume from any inoculum used in the culture
oxidized species ('532 patent, claim 19)	the variants of a protein formed by oxidation

Date: November 17, 2022

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